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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BALAJI VENKATARAMAN

Serial No. 10/635,428

Filed: August 6, 2003

For: VITAMIN COMPOSITIONS FOR THE  
TREATMENT AND PREVENTION OF  
VASCULAR DISEASE AND DEMENTIA

Art Unit: 1623

Examiner: ELLI PESELEV

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

I, Balaji Venkataraman, declare the following:

1. I am over the age of 21 and am competent to make this declaration based on personal knowledge.

2. I am the sole inventor of the subject matter disclosed and claimed in United States Patent Application Serial No. 10/635,428 filed August 6, 2003.

3. I am skilled in the art of preparing vitamin compositions for specified uses and have been active in this field for many years. I was previously Chief Operating Officer (2002- 2003), Chief Financial Officer (1999- 2002), VP Business Development, Strategic Planning and Operations (1998 -2000) at First Horizon Pharmaceutical Corporation (NASDAQ: FHRX). First Horizon, a specialty pharmaceutical company, markets, sells and develops brand name prescription products focused on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions. I was responsible for growing the company from an operating loss and sales of approximately \$5M, to, at its peak, an operating profit of approximately \$14M and sales of approximately \$115M in 5 years. In addition, I was responsible for in-licensing or acquiring over 15 drugs, commercializing 8 products, concluding 5 co-promotion agreements, and developing the company's product pipeline through partnerships with contract manufacturers,

JAN-20-2006 13:13

ALAVEN PHARM

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P.02

*U.S. Application Serial No. 10/635,428  
Declaration Pursuant to 37 C.F.R. § 1.132  
Page 2 of 4*

research organizations and drug development companies. I successfully took the company public and raised in excess of \$500M in debt and equity capital, and built the company employee base from approximately 70 people to approximately 300 people.

My previous experience includes: venture capitalist in managing specialty pharmaceutical and biotechnology investments for EJ Financial (Neopharm, First Horizon Pharmaceutical, ProtoMed), product management at Schering Plough (oncology drug Intron<sup>®</sup>A), Licensing and New Business Start-up at the University of Pennsylvania Center for Technology Transfer, Marketing Manager at Curative Technologies Inc. (marketing of wound care services and launch of autologous growth factor Procuren<sup>®</sup>), Technical Sales Representative for Millipore Corporation (purification equipment to pharmaceutical companies), Senior Research Chemist at Scios Inc (cardiovascular and inflammation product development).

I hold an M.S. degree in Organic Chemistry from Case Western Reserve University and an M.B.A. degree from the Wharton School of Business. I have several research publications, hold two patents and have several patent applications pending.

I helped develop prenatal vitamins at First Horizon Pharmaceutical Corporation— including the line extension to Prenate, the number one prescribed prenatal vitamin.

4. This declaration is submitted to provide evidence that the subject matter recited in claims 1-14, 18-22 and 24-27 of United States Patent Application Serial No. 10/635,428 is not obvious in view of Shapira (U.S. Patent No. 5,993,866, hereinafter Shapira) and European Patent No. 0 595 005.

5. I am familiar with prosecution of the present patent application and specifically with the Office Action of July 22, 2005, the response filed September 2, 2005, the Advisory Action mailed September 30, 2005, the Supplemental Response filed October 21, 2005 and the Advisory Action mailed January 17, 2006. I am also

JAN-20-2006 13:14

ALAVEN PHARM

6785890500 P.03

U.S. Application Serial No. 10/635,428  
Declaration Pursuant to 37 C.F.R. § 1.132  
Page 3 of 4

familiar with the outstanding obviousness rejection in view of Shapira and European Patent No. 0 595 005, and further declare that I have read these documents.

6. As one of ordinary skill in the art of preparing vitamin compositions for specified uses, I declare that disclosure of Shapira does not provide motivation to add magnesium to a composition containing B6, B12 and folic acid, such as the composition disclosed in European Patent No. 0 595 005. Shapira modifies a variety of foods and/or dairy products to reduce the ratio of methionine to B6 (mg/ml) below a starting ratio of methionine to B6 in the food. Examples 1-30 in Shapira disclose such ratios in cottage cheese, milk, cream cheese, chocolate, yogurt, sour cream, fish, sausage, chicken drumsticks and other foods. Shapira states at column 7, lines 53-61, that "The present invention thus consists in a variety of foods and/or dairy products in which the ratio methionine:Vit B6 (mg/mg) is reduced to below the starting (or base) methionine:vit B6 ratio..."

Food is a complex mixture of many compounds. Of particular importance to Shapira is methionine in food. Shapira adds folic acid, vitamin B6 and magnesium to food. As one of ordinary skill in the art, I declare that Shapira provides no suggestion or motivation to make vitamin compositions. Shapira modifies food to reduce the homocysteinogenic potential of food.

I further declare that Shapira, alone or in combination with European Patent No. 0 595 005, provides no suggestion or motivation to derive my claimed vitamin composition consisting of only the specified ingredients vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E. Methionine is absent from my claimed vitamin composition.

7. As one of ordinary skill in the art of preparing vitamin compositions for specified uses, I declare that the Shapira reference, concerning modifying the ratios of methionine to other factors in food to reduce the homocysteinogenic potential of food, is in another field that is separate and unrelated to the present field of preparing vitamin compositions. I declare as one of ordinary skill in the art of preparing

JAN-20-2006 13:14

ALAVEN PHARM

6785890500

P.04

U.S. Application Serial No. 10/635,428  
Declaration Pursuant to 37 C.F.R. § 1.132  
Page 4 of 4

vitamin compositions, that I do not peruse the literature concerning modification of food to reduce the homocysteinogenic potential of food. The Shapira reference is in a non-analogous area compared to the present invention directed to vitamin compositions and their use. Accordingly, as one of ordinary skill in the art of preparing vitamin compositions, I declare that I do not read art in the area of food modification and therefore would not be aware of the Shapira reference.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 1-20-06

  
BALAJI VENKATARAMAN

Attorney Docket: 52761-285976 (0100)